(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(e) These officials may not further redelegate these authorities.

Subpart G—Animal Drugs; Redelegations of Authority

§ 5.500 Issuance of Federal Register documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of section 512(a)(4) and (5) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(a)(4) and (5)). These officials may further redelegate this authority.

§ 5.501 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted under section 512 of the act (21 U.S.C. 360b):

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new animal drug applications that are described by section 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs under section 512(m) of the act (21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(e) These officials may not further redelegate these authorities.

§ 5.502 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted under section 512(m) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250);

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

(c) These officials may not further redelegate these authorities.

§ 5.503 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(D)(iv) and (c)(2)(F) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act (21 U.S.C. 360b(b)(2)), and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)):

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) These officials may not further redelegate this authority.

§ 5.504 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e), (m)(4)(B)(ii), and (m)(4)(B)(iii)) regarding the issuance of written notices:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

(b) These officials may not further redelegate this authority.

§ 5.505 Termination of exemptions for new drugs for investigational use in animals.

(a) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) These officials may not further redelegate this authority.

Subpart H—Radiation Control; Redelegations of Authority

§ 5.600 Variances from performance standards for electronic products.

(a) The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.